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*The National Professional  
Society of Pharmacists*

*Docket # 02N-0115*

**Statement of the  
American Pharmaceutical Association  
Before the Food and Drug Administration  
Center for Drug Evaluation and Research  
Risk Management of Prescription Drugs  
Public Hearing  
May 22, 2002**

Presented by Thomas E. Menighan, Pharmacist

Good afternoon. Thank you for the opportunity to present the views of the American Pharmaceutical Association (APhA), the national professional society of pharmacists. I am Tom Menighan, a long-time community and home-infusion pharmacy practitioner. For the last two years, I have been involved in the delivery of health information and tools to consumers and pharmacists via the Internet. I am the immediate past president of the APhA, and appearing today on the Association's behalf. APhA's more than 50,000 members are pharmacists providing care in all practice settings (such as community, hospital, long-term care, and hospice settings), pharmaceutical scientists and student pharmacists. In each of these settings, pharmacists help consumers manage and improve their medication use—and have an essential role in helping maximize the benefit and minimize the risk of medications.

My comments today will focus on a sub-set of the many questions posed in the April 15<sup>th</sup> announcement for this meeting. Specifically, I will discuss improvements for risk communication to pharmacists, comment on pharmacist-directed tools for risk management and propose options for optimizing the pharmacist's role in risk management.

My comments today are based on the perspective of the pharmacist as the medication use expert. Pharmacists fulfill an essential role in the health care system as the

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professionals, pharmacists have physical access to drug labels of nearly all products in their inventory,<sup>1</sup> an inventory including thousands of individual products. Pharmacists consider the drug product label a valuable resource.

We refer to prescription drug labeling information frequently as part of our normal pharmacy practice. In an informal survey conducted by APhA during the first four months of 2001, 30% of pharmacists responding stated that they access drug product labeling information several times a day, 36% access labeling at least once a day, and 34% access labeling information at least once a week. Respondents accessed labeling for a variety of reasons – to check for contraindications, verify dosage, examine potential warnings and adverse reactions, or to determine other available dosage forms. Respondents were most likely to refer to labeling for a recently approved product (48%) or when dispensing a drug for the first time (25%). Every time a product is dispensed (unless automation is used), pharmacy personnel handle the container with the product label. As we'll discuss later, that external label can be important for identifying certain categories of products as is done now with controlled substances.

According to the survey, pharmacists refer most often to the “Dosage and Administration” section, followed by the “Adverse Reactions” section as a close second. “Contraindications,” “Indications and Usage,” “Warnings,” “Precautions,” and “How Supplied” round out the top seven sections most frequently utilized. These are the same seven sections identified as the most important sections by physicians in a 1995 FDA survey, but in a slightly different order.<sup>2</sup>

The label physically attached to the product, though, does not always contain the most up-to-date information. The FDA receives more than 1,000 proposed labeling changes for approved new drug applications and biologics license applications each year.<sup>3</sup> There is a time lag between the review and approval of those proposed labeling changes, and when those changes appear on the product label as attached to the product in the pharmacy. The time lag, a result of production, distribution and dispensing cycles, may be extensive. And in the current labeling format, identification of those changes in the labeling is not easy.

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<sup>1</sup> In limited circumstances that drug label may not be available, such as when the label is provided to a patient upon request or the label is damaged.

<sup>2</sup> *Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels*, 65 FR 81082, at 81,084. December 22, 2000.

<sup>3</sup> *Requirements for Submission of Labeling for Human Prescription Drugs and*

In the current situation, then, we face a conundrum: we have physical access to drug information from the manufacturer and the FDA, but nothing confirming the currency of that information. This challenge, as well as challenges with the content and presentation of the information, diminish the labeling's utility. We support the Agency's investment of additional resources to improve product labeling.

Another problem exists when the risk communication tool of product labeling is combined with the risk management tool of restricted marketing. In a situation where pharmacists in certain practices are precluded from carrying certain products, they are also precluded from easily accessing the product information for those medications. At the same time, however, they may well serve patients who use the restricted products or have questions about them. Limiting access to product labeling is just one of the many problems with the current construct of restricted marketing. I will touch on more of those problems in a few minutes.

The move to electronic labeling, as proposed in the May 3, 2002 *Federal Register*, may offer some improvement to the current paper-based approach.<sup>4</sup> Requiring manufacturers to submit proposed labeling electronically is expected to shorten the review time needed to approve labeling changes and enhance the FDA's ability to ensure that all appropriate labeling changes have been made. When pharmacists can access the electronic labeling, the time lag for accessing information will decrease. (As an aside, the logistical issues within pharmacies must be an important consideration in the move to electronic labeling.)

As it is unlikely that paperless labeling will replace the current labeling construct in the near term, we support continued improvements to paper labeling and would be pleased to work with the Agency on such efforts. These changes include highlighting and prioritizing labeling modifications, as well as prominently date-stamping the labels to confirm the currency of the information.

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*Biologics in Electronic Format*, 67 FR 22367, at 22,368, May 3, 2002.

<sup>4</sup> *Id.*

### *Dear Health Professional Letters*

“Dear health professional” letters are another mechanism for communicating with pharmacists. While these documents can provide information in a timely manner, there are problems with document dissemination and information overload. In every pharmacy practice setting, time is at a premium and the need for quick access to accurate information is vital. One challenge with “Dear health professional” letters is that the communication may arrive in the pharmacy mail and be reviewed only once by the entire staff. Critical to success is the ability of multiple practitioners to assimilate the information contained in these letters in easily retrievable formats and to maintain the information for future access—when the pharmacist recalls receiving the information but would like to review the specifics of the communication. Chasing random pieces of paper is not easy in an office setting, and is obviously challenging in a pharmacy environment where more and more records are being stored electronically. In part because of this challenge, most pharmacists rely on the drug information contained in their pharmacy management systems, along with printed and bound references.

“Information overload” is more than just a buzz word for pharmacists. In the first 20 days of this month (May 1<sup>st</sup> to May 20<sup>th</sup>, 2002), seven dear health professional letters were distributed. If one extrapolates those 20 days to the 365 days in 2002, we could expect at least 127 communications to be sent—a figure that does not include additional separate communications from individual manufacturers. The twenty non-standard letters from this month ranged from warnings about counterfeit products to product recalls to changes in labeling. Unfortunately, the letters were not categorized to readily identify the importance or urgency of the information and thus are very difficult to assimilate, let alone recall days or weeks later. We urge the Agency to work with APhA and other pharmacist organizations to develop systems that can categorize the information, consistently highlight the most important content, and deliver it in ways to support reliable, standardized retrieval systems.

Posting this information on the FDA’s website and other frequently used websites is helpful, but many pharmacists do not yet have convenient access to the Internet in their practices. Certainly, pharmacies are increasingly capable of accessing the Internet and exploring this channel of communication will be essential, even in near term future systems’ decisions. However, in the

interim, we urge the FDA and the industry to work with APhA and vendors of pharmacy operating systems to explore mechanisms to integrate the content of “Dear health professional” letters into databases that “know” when to serve up the needed information or action at the appropriate time in normal pharmacy workflow.

### *Patient Communication*

The primary mechanism for manufacturers to communicate with patients is the patient package insert and the Medication Guide, as required in limited situations for drugs with serious and significant side effects. These mechanisms are not, however, the pharmacists’ primary mechanism for communicating with patients—that primary mechanism continues to be the one-on-one interaction between the health care professional and their patient. Written information can support that interface, but should not be considered a replacement for that interface. The communication between the pharmacist and the patient is vital to support patient understanding, particularly if products are being used for unlabeled indications. This is especially true for patients on complex regimens or therapies when patient and caregiver understanding can have such a major impact on appropriate use.

An additional consideration for consumers is the impact of direct-to-consumer advertisements of prescription medications. The prevalence of DTC-advertising is obvious to any of us watching television or reading magazines—a recent survey by the Kaiser Family Foundation found that 91% of all Americans have seen or heard a DTC advertisement for a prescription drug<sup>5</sup>—but the benefits and potential risks of this expansion are not so readily observable. It is unclear if consumers retain adequate information from a DTC ad, including a clear understanding of the drug’s risks and benefits. Are DTC ads increasing consumer and health professional dialogue? Has the explosion of DTC advertising yielded an improvement in medication use, either through improved compliance or by stimulating consumers to seek medical care for untreated conditions? Or, by contrast, has the DTC explosion yielded an increase in the “casualness” with which our society perceives medication—that there is a tablet to treat everything, and all I must do is ask

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<sup>5</sup> Kaiser Family Foundation. “Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising, and Prescription Drug Trends—A Chartbook Update.” November 2001.

my doctor to get it? These questions must be answered, as DTC ads are another communication mechanism, another important factor in building an improved risk management system.

### Enhancing communication about safety and efficacy

#### *Computer-generated alerts*

A common method for communicating drug information to pharmacists in all practice settings is through computer programs to aid in screening multiple drug regimens for conflicts—the drug utilization review programs within pharmacy computer systems. And many manufacturers are including these messaging capabilities in proposals to manage product risk and communicate information. Care must be exercised to reduce noise in these systems before using this mechanism as a component of risk management programs.

These systems provide information to the pharmacy staff at the point of product dispensing and for this reason can be a valuable component of risk management. The drug product and prescribed dosing are compared to databases to identify “abnormalities”, warnings, and drug interactions. These messages are then provided to the pharmacist or pharmacy technician for consideration in preparing the prescription and securing payment from third-party payors. For those of us who use word processing programs in our daily work, the systems are somewhat analogous to the “spell-check” function in those programs.

Unfortunately, these systems suffer from the same problems as the numerous “Dear health professional” letters—too much information without sufficient prioritization or stratification. In one observational study, more than 80% of the alerts generated by these systems were overridden by the pharmacist.<sup>6</sup> That is a staggering percentage, and a signal of a problem that must be addressed. It is not necessarily true that bad decisions are being made. Rather, system vendors often have a bias to protect themselves legally by warning of every possible negative event without regard for the need to prioritize those messages in busy practices. Can you imagine if the spell-check on your computer was wrong 60% of the time? If that were true, you and I would probably shut off this function or ignore it.

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<sup>6</sup> Chui MA, Rupp MT, “Evaluation of online prospective DUR programs in community pharmacy practice,” *J Managed Care Pharm* (2000): 6:27-32.

Beyond the noise factor, these alerts also pose problems with significant variability among pharmacy operating systems, among third party plans and with PBM-generated alerts. In an analysis of one set of alerts from 17 state Medicaid programs, the inconsistency was clear. Out of 23 possible alerts, only 5 were included by a majority of the states in their systems. No two states used identical criteria sets, even if the same software vendor supported both programs. The alerts provided by different vendor systems vary widely, so a pharmacist addressing the same clinical situation may get a different alert from one program than from another.<sup>7</sup> Clearly, this inconsistency is not good for pharmacy practice, risk management, or for clearly communicating risk information.

The profession is working to improve these systems, both to decrease the noise and increase the consistency of criteria used to generate messages. As the Agency evaluates risk communication mechanisms, the current limitations of these alert systems must be recognized. Capabilities should be explored and utilized, but not without recognition for workflow issues in busy practices.

#### Other steps to communicate risk and benefits

It is clear that relying on existing mechanisms for benefit and risk communication is insufficient. As more and more information bombards pharmacists and their patients, there must be a way to readily identify the source of information, as well as the relative priority and urgency. APhA suggests the Agency work with pharmacist organizations to develop communication structures that meet these needs. We look to our professional organizations for guidance on many issues. By building on existing partnerships among the Agency, the manufacturers and these groups, risk communication will be enhanced.

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<sup>7</sup> The U.S. Pharmacopoeia Drug Utilization Review Advisory Panel. Drug utilization review: mechanisms to improve its effectiveness and broaden its scope. *J Am Pharm Assoc* (2000);40(4):538-45.

One mechanism to consider is creating a new classification scheme for prescription drugs, under which higher risk products would be identified as belonging to a category of drugs which demand special attention from clinicians and patients. This new risk stratification schedule would be analogous to the schedules defined in the Controlled Substances Act. Health professionals would know that a drug in the high risk category bears special or unusual risks that require close monitoring. When one pulls a schedule II narcotic off the shelf for dispensing, it is easy to see the “CII” on the label. A similar, large and bold notation on the label of products requiring additional risk management could be quite useful.

### ***Tools for Risk Management, including Restricted Marketing***

APhA urges the FDA and product sponsors to evaluate closely the role of the pharmacist in risk management. We can play a vital role in helping consumers make the best use of their medication, but unfortunately we are often bypassed in risk management systems or relegated to positions that minimize the contribution we could make. I will first discuss some of the challenges pharmacists face with FDA’s current methods for managing risk, and then articulate some recommendations for improving these interventions.

In the last 20 years, 14 drugs that had received FDA approval and were on the market were later withdrawn for safety reasons. This action, usually voluntary and in cooperation with the FDA, is an indication that post-marketing systems to monitor adverse drug reactions are functioning. The loss of these products can also, at least in part, be attributed to the health care system’s failure to appropriately manage drugs. Despite the FDA’s efforts to change the actual use of medications, the role and effectiveness of the FDA in this area is limited. Practitioners and consumers must also participate.

For example, Propulsid® (cisapride) was approved in 1993 for treatment of severe nighttime heartburn in patients with GERD. Seven years later the drug was withdrawn from general distribution after adverse event reports showed evidence that the drug caused an abnormal heart rhythm in many patients—some of which resulted in the patient’s death. However, a majority of



patients experiencing adverse events had identifiable risk factors such as pre-existing heart disease or were taking multiple medications. Also in 2000, the irritable bowel syndrome medication Lotronex® (alosetron hydrochloride) was taken off the market after adverse event reports showed evidence of ischemic colitis—intestinal damage resulting from reduced blood flow. Although the drug was only indicated for diarrhea-predominant IBS, many of the adverse events were found in patients with constipation-predominant IBS who should never have received the medication. In these situations, patients lost access to a number of valuable medications because the health care system failed to appropriately manage risk.

This reality creates an opportunity for pharmacists and the FDA to work together, focused on the profession's goal to help patients make medications work. Unfortunately, a primary barrier to pharmacists' participation in risk management occurs when restricted marketing is used and pharmacists are excluded from working with the product. Restricted marketing, as currently used by the Agency, causes significant concern in the pharmacy community. Arbitrarily restricting products to certain providers creates problems for both health care professionals and patients: posing substantial risks, including problems with drug interaction checking, product availability, and communication with their prescriber and pharmacist of choice.

In the typical restricted marketing situation, pharmacists cannot fulfill their role in helping patients make the best use of their medications because they cannot access the product. The one-on-one communication I discussed earlier —a vital component to the consumer fulfilling their role as a risk manager —is disrupted when pharmacists are excluded from working with certain drugs. Restricted marketing disrupts existing pharmacist/patient relationships and disaggregates care from existing providers. The structure requires multiple clinicians to get involved in patient care, each having access to only a portion of the relevant record. Disrupting an already fragmented health care system does not support patient care nor risk management.

APhA has vehemently opposed restricted marketing since before this Agency was founded — APhA's support for the Federal Food, Drug and Cosmetic Act in 1938 was based on concern for the public health and support for distributing medication through pharmacies with the

involvement of pharmacists. In the 1970s, APhA challenged the Agency's restrictions on methadone in court ... and won. As expressed in an editorial from 1973, the profession is concerned that FDA may decide that "only blue-eyed, red-haired, left-handed pharmacists" are entitled to possess and dispense some medications.<sup>8</sup> And while I happen to be one of the very few pharmacists who would meet such criteria, the problems with such an approach are clear.

Although the Agency apparently sees some advantage in restricted marketing, perhaps in data collection, the risks of this approach outweigh any perceived benefits. A new approach, one that builds on the pharmacists' role rather than eliminating or limiting it, could be structured to yield necessary data collection.

Some skeptics may challenge this appeal by noting that pharmacists are paid to dispense medications, and asking them to fulfill any other role is simply not feasible. This comment is important, because if the system needs pharmacists to fulfill an expanded role in the medication use process, those activities must be compensated. Deploying pharmacists to help manage risk is a necessary change, but one that requires not only a change in focus but also a change in payment. And that responsibility extends beyond the agency to third party payors, manufacturers and others in the health care system ... others who pay (financially) for the consequences of mis-used medications must proactively invest in the pharmacist and activist patient.

A third challenge emanates from the current product-by-product approach to risk management program development. When challenges are identified with one product, a new program is developed to address the identified problems, with little if any similarity to existing programs. This product-by-product approach may yield success for a specific product, but that success is short-lived in the real world as the Agency uses such programs with increasing frequency. Pharmacists become faced with a thalidomide program, a clozapine program, an isotretinoin program, and the list continues.

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<sup>8</sup> Griffenhagen G, "The Blue-Eyed, Red-Haired, Left-Handed Pharmacist", *J Am Pharm Assoc* (1974): NS14 (8):399.

Different FDA-mandated programs for different medications make the problem of medication use more complicated. Physicians and pharmacists must manage a different and sometimes conflicting set of requirements for different products, focusing interest and attention on red tape rather than appropriate medication use. While a program may work to manage risk for one medication, combining that program with different programs for different products generates a confusing environment. For example, a patient registry operated through one program may have entirely different requirements and procedures from a patient registry for a different medication. Such inconsistency frustrates participating health professionals, and may defeat the goal of risk management. For pharmacists, these requirements begin to resemble the myriad of third party payor policies and formulary requirements. At a time when we should be capitalizing on the patient care capabilities of pharmacists, we are instead layering new administrative burdens on them: relegating pharmacists to paper pushers rather than providing patient care.

Finally, the standards for determining when products should be placed into various risk management programs are not clear. The current process gives the impression that the Agency holds products hostage until the manufacturer agrees to distribution restrictions. Why are some products subject to substantial risk management interventions, while others with a seemingly similar risk profile are not? This creates confusion in the pharmacy, and may yield situations where patients are moved from one product to another because of a decrease in the administrative burden rather than clinical superiority.

### *Suggestions for Risk Management Tools*

We have evaluated many of the challenges with existing risk management tools, and propose the following principles to improve risk management interventions.

#### Criteria to determine when a product should be used

The first step to improving the risk management tools should be the identification of criteria to determine when formal risk management tools will be used. While all drugs have risks, there is

no delineation within the prescription medication class to identify those products that may have a higher risk, require more attention, or special patient screening. A collaborative effort by the Agency, manufacturers, health professionals and consumers could outline a mechanism to facilitate this process. Identifying what would trigger the need for a formal risk management system should yield more consistency in the marketplace, and help health professionals and consumers deal with these products appropriately.

This initiative would help avoid a situation where all products are required to use all risk management tools on the theory that if something is good for one medication, it must be good for all. If all new products are directed into a program such as this, the enhanced program would lose its effectiveness: an advantage of additional oversight exists because the program is not used for most available products.

#### A systems approach

The second principle is the need to address risk management in a systems-based approach, recognizing that the current product-by-product mechanism must operate in a broader health care system. We recommend developing a standardized process to work with medicines demanding special attention, as identified by the process just suggested. As a mechanism to help pharmacists and other health professionals distinguish these products from prescription medications, products using this system could be placed in their own sub-set of the prescription medication class, readily identifying them as requiring a formal risk management system. This approach is analogous to controlled substance scheduling, where pharmacists and other health care professionals readily identify the requirements for products dependence potential.

The broad system would consist of a number of tools, such as category labeling, targeted education, registries, laboratory test validation, and periodic medication monitoring. Each program would be built from those tools, creating a program to manage a specific medication. For example, the risk management program for a medication requiring specific laboratory tests to detect adverse effects would involve documentation of such testing. Such documentation by both the prescriber and the pharmacist helps confirm the completion of the work, and underscores the importance of the testing with the consumer. A program requiring patient education would have pharmacists document their interaction with the patient and the patient's understanding.

The system provides consistency to the risk management programs: if, for example, a patient registry is required, the registry would operate in a similar manner across all programs. This would limit the administrative burden and total barriers to entry generated by multiple programs, and helps pharmacists and other health care providers focus on the patient rather than the administrative hoops. Additionally, success of these tools will require revising the payment system to properly compensate pharmacists and other health care professionals for their contributions to the success of risk management activities.

We must still exercise caution in determining what tools will be used in the system. In an effort to establish consistent programs, there will probably be a desire to take the latest idea for risk management and apply it to every relevant drug. It will be essential to match the system tool to the identified risk, as well as to evaluate the effectiveness of the tools. Health professionals

would know that drugs in the high-risk category bear special or unusual risks that require close monitoring—and common program elements would allow health care providers to build these services into their practices.

### Opt-In Program

Quite simply, restricted marketing must be re-evaluated. An appropriate alternative is an opt-in program, one where physicians and pharmacists agree to comply with risk management tools, rather than a manufacturer's or regulator's limitation of product distribution. This scenario allows prescribers and pharmacists to maintain relationships with their patients; it allows every pharmacist to choose whether or not to work with these products. Such programs ensure medication access to those pharmacists and other providers willing to meet legitimate use and monitoring requirements—but do not arbitrarily limit health care provider participation.

### Pulling the principles together

Let me explain how such a system could work with a hypothetical Drug A, a fictitious product requiring liver-function testing after three months of therapy. The first step in the process would require the product sponsor and the agency to determine, according to the established criteria, that the product requires a risk management system. Drug A would then become part of the identified sub-class of prescription drugs, readily identifying to pharmacists and other health care professionals its inclusion in a risk management system.

The program to manage the product would then be developed, with two risk interventions used: patient education and confirmation of patient testing. These interventions would be the same as

any other system products requiring the same intervention. Documentation of compliance with the intervention tool would be accomplished through a central system, and payment for the interventions could be accomplished through the same system. With an opt-in program, any pharmacist or health care professional would be eligible to work with the product, providing they agree to comply with program requirements.

Using these principles to develop new and integrate existing risk management tools will help support the activity of patients, pharmacists, and other health care professionals.

### ***Evaluation of Risk Management Strategies and Interventions***

In the announcement for this meeting, the Agency asked what risk management interventions should be studied for effectiveness. The answer is simple: all of them. Such evaluation is essential to the success of the interventions, and important as new interventions will likely be adopted in new programs but their success should be demonstrated prior to broad adoption. This evaluation must include analysis of how the program is working in pharmacy practice, including all pharmacy environments. A challenge with some existing programs emanates from the apparent focus on a limited number of pharmacy environments, such as the community or hospital setting, to the exclusion of other settings. Pharmacists work with patients in a number of different settings and the impact of a program must be analyzed in each of these.

The evaluation is essential to the expansion of the tool to other programs. It appears that the sticker component of the program to reduce fetal exposure to isotretinoin is being thought of by some as the “holy grail” in risk management. Unfortunately, anecdotal reports by pharmacists

suggest significant dissatisfaction with the program. We do not know whether the intervention is effective, and that effectiveness and impact on pharmacy and medical practice should be evaluated before the tool is widely adopted. We applaud the product sponsor for their attempts to protect the consumer, including the substantial problem of dealing with a product already in wide use, but we have significant concerns that the sticker program will be used broadly before the effect of the program has been shown. Rigorous evaluation of existing interventions and any proposed tools is essential.

Ongoing analysis is also necessary to refine risk interventions, as expanded product experience may demonstrate that the medication no longer meets the criteria requiring a formal risk management system. Just as post-marketing surveillance can identify problems, a formal risk management program may identify a smaller number of expected problems and the opportunity to transition out of the specific classification.

Letters and stickers as risk management tools are too often "sticks in the spokes" of most pharmacy operations. The technology exists today, and the will exists today, to create a way to preserve access to good drugs with special requirements. With the help and commitment of FDA and industry, pharmacists are prepared to play an increasing role in risk management, but that role requires improved risk communication, standardization of risk management interventions, and payment for those services. Thank you for the opportunity to present the views of the nation's pharmacists on these important issues. I look forward to working with the Agency and other stakeholders on these important issues.





## FDA Hearing on Risk Management

Tom Menighan, RPh, MBA  
American Pharmaceutical Association  
May 22, 2002

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## Risk Communication

- For pharmacists to play a role, must understand risk communication
- Challenges with risk communications
  - Volume of Dear Pharmacist letters
  - Clarity of communications
  - “Noisy” on-line drug utilization review systems
    - 88 1% of messages over-ridden
- Need to prioritize and highlight new information

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## Challenges with current risk management tools

- Excluded from handling product
  - Specific pharmacy distribution mechanisms
  - Pharmacy excluded for focus on prescriber
- Financial structure
  - Primary payment based on order fulfillment, structure supports fulfilling orders, with disincentives to limit or intervene in product use
- Product-specific programs with little similarity
  - Lack of standardization yields more focus on the administration requirements than on the product risk

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### Managing the Risk and Maximizing the Value...

- Criteria to identify appropriate products for the system
- Systems approach
- Opt-in program
- Match identified risk to tools used

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### The future...

- Common utility to manage products with specific risks
- Maximize pharmacist contribution
- Improve medication use, maximize the benefits

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